

REMARKS

Status of Claims and Amendment

Claim 7 has been amended. Claims 8-14, 16, and 17 have been canceled. New claims 18-22 have been added. Claims 7, 15 and 18-22 are all the claims pending in the application. Claims 7, 13, 15, and 17 are rejected.

Claim 7 has been amended to replace “homology” with “identity” and to incorporate the limitations of claim 13.

Support for new claims 18, 19, and 21 can be found for example at least at page 11, 1st paragraph, page 18, lines 20-28 and page 22, lines 16-26 of the specification.

Support for new claims 20 and 22 may be found throughout the specification and original claim 1.

No new matter is added.

Claim of Priority

Applicant thanks the Examiner for acknowledging Applicant’s claim of priority to Japanese Application No. 2002-265622 filed September 11, 2002, and Japanese Application No. 2003-56813 filed March 4, 2003, as well as receipt of the certified copies of the priority documents.

Information Disclosure Statement

Applicant thanks the Examiner for acknowledging the Information Disclosure Statement filed March 3, 2008, by returning a signed and initialed copy of the PTO Form SB/08 that accompanied the filing.

Elections/Restrictions

The Examiner has withdrawn claims 8-10 as being directed to a non-elected invention.

Solely to advance prosecution of the present application, Applicants have canceled claims 8-10.

Withdrawn Rejections

Applicants thank the Examiner for withdrawing the rejection to claims 7 and 13 under 35 USC § 112, first paragraph, for the reasons stated at page 4, 1st full paragraph of the Office Action.

Response To Double Patenting Rejection

Claims 7, 13, 15, and 17 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19 and 21-25 of copending Application No. 10/975367.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In response, Applicants respectfully request that the rejection be held in abeyance.

Response To Claim Rejections Under 35 U.S.C. § 112

Claims 7 and 13 are rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite.

The Office Action asserts that the recitation of “homology” in claims 7 and 13 is indefinite because it connotes a qualitative relationship having some evolutionary component and does not definitively describe the metes and bounds of the claimed invention. The Office Action appears to suggest amending the claims to recite “identity” because such a term has a quantitative relationship that can be mathematically calculated. The Office Action has interpreted claim 7 to recite a polypeptide consisting of an amino acid sequence having 95% or

greater identity with that of SEQ ID NO: 2 or 4, and exhibiting an activity of promoting insulin production by activation.

In response, Applicants note that the claims prior to the present amendment clearly define what Applicants consider to be the claimed invention. However, solely to advance prosecution of the present application, claim 7 has been amended to replace “homology” with “identity” in order to address this rejection.

Claim 13 has been canceled. Accordingly, the rejection with regard to claim 13 is rendered moot.

Reconsideration and withdrawal of the rejection under § 112, second paragraph, is respectfully requested.

Response To Claim Rejections Under 35 U.S.C. § 102

Claims 7, 13, 15, and 17 are rejected as being anticipated by Chen et al. (U.S. Patent No. 7,108,991; “Chen”), for the same reasons of record.

In addition, the Office Action asserts that Applicants’ arguments are not persuasive because, as mentioned in the Advisory Action mailed January 30, 2008, “regulation” may be either increasing or decreasing the amount of the compound of interest and would encompass increasing insulin.

The Office Action asserts that Applicants’ arguments that the date of Chen does not antedate the instant disclosure are not persuasive because the filing date of the disclosure of Chen has been accorded the provisional filing date which is before the earliest filing date of the instant application. Also, the Office Action asserts that the Chen provisional application states (at pages 14 and 19, for example) that the RUP3 protein can be used to screen candidate

compounds and provide for the direct identification of candidate compounds, agonists, inverse agonists, and partial agonists, which act at this cell surface protein.

Initially, Applicants note that the Office Action has misapplied the standard for maintaining an anticipation rejection under §102 because “[i]n order to anticipate the claims, the claimed subject matter must be disclosed in the reference with sufficient specificity to constitute an anticipation under the statute [emphasis added].” M.P.E.P. § 2131.03. In the present case, Chen does not disclose or even suggest measuring the production or amount of insulin, and at best, merely discloses that RUP3 is expressed in the pancreas. The inconclusive data disclosed by Chen does not show whether RUP3 is involved in endocrine or exocrine function because Chen takes no further steps to measure insulin production or the amount of insulin, which is required for the claimed invention. Thus, the measurement of insulin is not a necessary element to carry out the screening method of Chen which merely screens candidate compounds that act at the cell surface protein, and measures the levels of cAMP to determine the ability of the compound(s) to inhibit or stimulate the G-protein coupled receptor. (See column 5, lines 26-31, and columns 6-7 of Chen).

Instead, the Office Action appears to rely on the statement in Chen that “RUP3 is expressed within the human pancreas, suggesting that RUP3 may play a role in insulin regulation [emphasis added].” (See column 5, lines 62-64 of Chen). Such a “suggestion” is an improper standard to show that a claimed invention is anticipated, and such “suggestion” is insufficient evidence to show that the missing descriptive matter, i.e., increased insulin production, is necessarily present in the reference and that the increase in insulin production would be recognized by one of ordinary skill in the art as a necessary element for the method disclosed by Chen to screen candidates to determine whether the candidates inhibit or stimulate the cell

surface protein or G-protein coupled receptor. M.P.E.P. § 2131.01. Further, there is no reason to confirm whether the substance specifically increases insulin production. Thus, this step, now recited in claim 7, is not inherent in Chen. Accordingly, Chen does not explicitly or inherently disclose the presently claimed invention.

Claims 13 and 17 have been canceled. Accordingly, the rejection with regard to claims 13 and 17 is rendered moot.

Reconsideration and withdrawal of the rejection under § 102(e) is respectfully requested.

The Examiner's attention is also directed to new claims 18-20, which recite a specific amount to which the polypeptide is activated and how the polypeptide is analyzed.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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